

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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In Re: PHARMACEUTICAL INDUSTRY	:	
AVERAGE WHOLESALE PRICE	:	
LITIGATION	:	
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THIS DOCUMENT RELATES TO	:	MDL NO. 1456
	:	
<i>State of Montana v. Abbott Labs., Inc., et al., 02-</i>	:	Master File No. 01-CV-12257-PBS
<i>CV-12084-PBS</i>	:	
	:	Judge Patti B. Saris
	:	
<i>State of Nevada v. American Home Prods. Corp.,</i>	:	
<i>et al., 02-CV-12086-PBS</i>	:	
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<i>County of Suffolk v. Abbott Laboratories, Inc., et</i>	:	
<i>al., 01-CV-12257-PBS</i>	:	
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**DEFENDANTS' BRIEF IN RESPONSE TO THE AMICUS CURIAE BRIEFS OF
THE UNITED STATES AND THE COMMONWEALTH OF MASSACHUSETTS**

TABLE OF CONTENTS

	<u>Page</u>
ARGUMENT	4
I. THE “PRESUMPTION AGAINST PREEMPTION” DOES NOT APPLY BECAUSE, AS IN <i>BUCKMAN</i> , BEST PRICE CLAIMS INVOLVE THE ACCURACY OF DATA SUBMITTED TO A FEDERAL AGENCY	4
II. STATE LAW BEST PRICE CLAIMS ARE PREEMPTED BECAUSE AN EXTENSIVE MECHANISM FOR FEDERAL ENFORCEMENT EXISTS AND PERMITTING THE CLAIMS WOULD UPSET THE DELICATE BALANCE OF FEDERAL STATUTORY OBJECTIVES	10
CONCLUSION.....	16

TABLE OF AUTHORITIES**CASES****Page**

<i>Abdu-Brisson v. Delta Air Lines, Inc.</i> , 128 F.3d 77 (D.C. Cir. 1997).....	5
<i>Boyle v. United Technologies Corp.</i> , 487 U.S. 500 (1988).....	10
<i>Buckman Co. v. Plaintiff's Legal Committee</i> , 531 U.S. 341 (2001).....	<i>passim</i>
<i>Crosby v. National Foreign Trade Council</i> , 530 U.S. 363 (2000).....	5
<i>Gade v. National Solid Wastes Mgmt. Ass'n</i> , 505 U.S. 88 (1992).....	11
<i>Garner v. Teamsters</i> , 346 U.S. 485 (1953).....	3, 14
<i>Grant's Dairy Maine LLC v. Commissioner of Maine Dep't of Agriculture</i> , <i>Food & Rural Resources</i> , 232 F.3d 8 (1st Cir. 2000).....	10
<i>InterGen N.V. v. Grina</i> , 344 F.3d 134 (1st Cir. 2003).....	10
<i>Matz v. Household Intern. Tax Reduction Inv. Plan</i> , 265 F.3d 572 (7th Cir. 2001)	3
<i>McCarty v. Azure</i> , 22 F.3d 351 (1st Cir. 1994).....	10
<i>Pennsylvania v. Nelson</i> , 350 U.S. 497 (1956).....	15
<i>PhRMA v. Concannon</i> , 249 F.3d 66 (1st Cir. 2001).....	4
<i>PhRMA v. Meadows</i> , 304 F.3d 1197 (11th Cir. 2002)	4
<i>PhRMA v. Thompson</i> , No. 03-5117 (D.C. Cir. April 2, 2004).....	4

<i>PhRMA v. Walsh</i> , 538 U.S. 644 (2003).....	4
<i>San Diego Building Trades Council v. Garmon</i> , 359 U.S. 236 (1959).....	15
<i>Skidmore v. Swift</i> , 323 U.S. 134 (1944).....	3
<i>Verizon Commun., Inc. v. Law Offices of Curtis V. Trinko, LLP</i> , 124 S. Ct. 872 (2004).....	6

STATUTES

42 U.S.C. § 1320(a)(7)	7
42 U.S.C. § 1396r-8(b)(3)	7, 12
42 U.S.C. §§ 256b(a)(1)-(2).....	13

MISCELLANEOUS

Brief for the United States in <i>Buckman Co. v. Plaintiff's Legal Committee</i> (Sept. 2000) ... <i>passim</i>	
CMS, <i>Best Practices Guide for Dispute Resolution</i> (1999)	8
CMS, <i>Medicaid Drug Rebate Operational Training Guide</i> (Sept. 2001)	9
HCFA/CMS <i>Medicaid Drug Rebate Program Release No. 19</i> (Oct. 15, 1995)	8
HCFA/CMS <i>Medicaid Drug Rebate Program Release No. 71</i> (Nov. 20, 1997)	9
HCFA/CMS <i>Medicaid Drug Rebate Program Release No. 86</i> (Dec. 11, 1998).....	9
HHS OIG, <i>Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs</i> (May 8, 1998)	8
68 Fed. Reg. 51912 (Aug. 29, 2003).....	7
60 Fed. Reg. 48465 (Sept. 19, 1995)	7

Taking the second of the Court's questions first, the Government confirms that it can enforce, and has enforced, federal law to provide States with full relief for violations of the best price obligations imposed by federal law and the manufacturer contracts with HHS. *See* Amicus Brief of the United States ("Govt. Br.") at 20. Indeed, the Government touts the fact that even if the States do not join a "federal suit [for violations of the federal rebate obligations], the states would benefit as they would receive an additional rebate payment from the manufacturer if the United States prevailed at trial." *Id.* Likewise, in its amicus brief, Massachusetts acknowledges that it recovered its full Medicaid share of more than \$5.4 million recently in "two nationwide" Medicaid rebate settlements, even though those two matters were handled and enforced by the Department of Justice ("DOJ") under federal law. *See* Memorandum Amicus Curiae of the Commonwealth of Massachusetts ("State Br.") at 2. Therefore, the concern expressed by Massachusetts, Montana, and Nevada, that their interests somehow might not be protected if state law best price claims were preempted, is unfounded. Even if the state law claims are preempted, the States will still be able to assist DOJ in its investigation of violations of federal law, and the States will obtain full relief if DOJ "prevails at trial" or the matter is settled, just as Massachusetts has in these two recent federal best price investigations.

With respect to the Court's preemption question, the Government ignores the exclusively federal components of the Medicaid *rebate* program in favor of general exhortations about the States' traditional role in enforcing "Medicaid fraud" statutes and participating in the "cooperative state-federal" Medicaid program. Govt. Br. at 7-8. But the States have virtually no role in the Medicaid rebate program, the program at issue in *this* case, in contrast to other aspects of the Medicaid program. For example, the States have never initiated any enforcement action, up until this case, in the 14-year history of the Medicaid rebate program. Likewise, even though

the States have a traditional role in enforcing violations of their state Medicaid plans, the state Medicaid plans of Massachusetts, Nevada, and Montana contain nothing -- not a word -- about manufacturer obligations to HHS under the rebate program. This is because HHS and CMS run and enforce this program, a fact that neither the Government nor the States dispute.

First, as the Government concedes, the rebate statute and the HHS Rebate Agreement, not state law, define “best price” and establish the obligation of a manufacturer to report best prices to CMS (Govt. Br. at 3). Second, HHS establishes the amount of the rebates owed and treats the best price data as confidential information not released to the States. *Id.* Third, HHS and CMS, not the States, interpret the rebate statute and provide interpretive guidance to manufacturers and the States. Fourth, HHS and CMS, not the States, have established a dispute resolution process for disputes between the manufacturers and the States. Fifth, the rebate statute and the Rebate Agreement provide HHS and CMS, not the States, with the power to conduct surveys and audits to verify best prices and to punish manufacturers who submit false information to HHS. *Id.* at 5. Under *Buckman Co. v. Plaintiff’s Legal Committee*, 531 U.S. 341 (2001), this kind and extent of federal control over the program and statutory regime preclude the traditional “presumption against preemption.” *Id.* at 347. In fact, the case against this “presumption” is even stronger because the state law claims here, unlike those in *Buckman*, depend entirely on obligations that flow from contracts with the federal government, a fact that the Government remarkably ignores.

Equally unavailing is the Government’s attempt to distinguish *Buckman* on the ground that the States have a “common interest” with the Government in prosecuting Medicaid fraud and in the submission of accurate best price data. The mere existence of arguably concurrent state interests does not diminish the fact that the States’ best price claims turn on the

accuracy of data submitted *only* to a federal agency pursuant to contracts with that agency.

There is no escaping the fact that this is a fraud-on-CMS case. The argument for preemption is not weakened simply because the Justice Department believes that States might usefully supplement the existing and extensive federal audit, investigative, and enforcement powers.¹

The Government also concedes, but shrugs off, the many obstacles that state law best price claims would pose to the administration of the Medicaid drug rebate program. *See* Govt. Br. at 15-18. For example, the Government admits that best price claims would require manufacturers to file “state-specific best price reports” (*id.* at 16-17), but ignores the fact that, by statute, CMS must calculate the rebates using single, nationwide best prices. Best prices cannot be made “state-specific” without the total reinvention of the Medicaid drug rebate program. The Government also admits that state law best price claims would permit courts in all 50 States to reach different conclusions about the calculation of best prices (*id.* at 17), but asserts that national uniformity nonetheless will be preserved because state courts “naturally” will defer to “guidance” from CMS. *Id.* at 18. This contention is plainly unrealistic and contrary to what the Government told the Supreme Court in *Buckman*, where it advocated preemption precisely because “a multiplicity of tribunals . . . are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law.” Brief of the United States in *Buckman* (Sept. 2000) at 23 (“*Buckman* DOJ Br.”) (quoting *Garner v. Teamsters*, 346 U.S. 485, 490-91 (1953)).

¹ The Justice Department’s views, of course, are not entitled to controlling or substantial weight. *See, e.g., Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (declining to adopt the views of a federal agency expressed in an amicus brief); *Matz v. Household Intern. Tax Reduction Inv. Plan*, 265 F.3d 572, 575 (7th Cir. 2001) (same).

ARGUMENT

I. THE “PRESUMPTION AGAINST PREEMPTION” DOES NOT APPLY BECAUSE, AS IN *BUCKMAN*, BEST PRICE CLAIMS INVOLVE THE ACCURACY OF DATA SUBMITTED TO A FEDERAL AGENCY.

The Government asserts that the traditional “presumption” against implied conflict preemption should apply here because the States have a traditional role in enforcing statutes against Medicaid fraud and share an interest in accurate best price reporting to HHS. *See* Govt. Br. at 8-9. But as noted at the outset, the States have no traditional role in enforcing the HHS Agreement under the Medicaid rebate program. Instead, the States’ enforcement role in the Medicaid program relates principally to enforcing compliance with state Medicaid plans, which are silent as to manufacturer compliance with HHS Medicaid rebate obligations. The States do indeed have “flexibility in tailoring the scope and coverage of their state plans” (*id.* at 2), but this case is not about the States enforcing violations of a provision in their state Medicaid plans. Likewise, the Government disingenuously references supplemental drug rebate agreements between particular States and drug manufacturers (*id.* at 4), but these agreements are not at issue here. Unlike the manufacturer-HHS Agreement, supplemental rebate agreements are between manufacturers and States, not the federal government. Likewise, state “prior authorization programs” and “drug formularies” (*id.*) also are not at issue.²

² For this reason, the Government’s reliance (Govt. Br. at 8) on *PhRMA v. Concannon*, 249 F.3d 66 (1st Cir. 2001), *aff’d sub nom. PhRMA v. Walsh*, 538 U.S. 644 (2003), and *PhRMA v. Meadows*, 304 F.3d 1197, 1206 (11th Cir. 2002), is completely misplaced. These cases did not involve preemption under the Medicaid rebate program or claims involving fraud on a federal agency. Likewise, the recent D.C. Circuit decision rejecting a challenge to a Michigan statute that established a formulary under a state Medicaid plan is also irrelevant. *See PhRMA v. Thompson*, No. 03-5117 (D.C. Cir. April 2, 2004).

Even though the States may share an interest in seeing the federal government obtain accurate best price data, the States' claims turn on the accuracy of data submitted to HHS. There is simply *no* avoiding this basic fact, as the best price reports are submitted to HHS (and only HHS) in accordance with definitions and rules established *exclusively* by federal law and federal contract. Unlike the traditional Medicaid fraud case, the States' best price claims are not based upon provider claims made to the State or submitted in violation of the rules set forth in state Medicaid plans. Where, as in this case, the state law claims are based on "[p]olicing fraud against federal agencies," which is "hardly a field which the States have traditionally occupied," the *Buckman* Court could not have been clearer: the usual "presumption against finding federal preemption of a state-law cause of action" does not apply. 531 U.S. at 347. In fact, just as in *Buckman*, the States' best price claims could not exist but for the rebate statute and the HHS Rebate Agreement. *Id.* at 353 ("the fraud claims exist solely by virtue of the [MDA] disclosure requirements.").

The Government disregards the admonition in *Buckman* that the "relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347 (citation omitted). The fact that the States may also have interests consistent with those of HHS does nothing to diminish the fact that for purposes of the Medicaid rebate program, the manufacturers are regulated by CMS and the rebate program is "inherently" federal and "governed by" federal law. *See Crosby v. National Foreign Trade Council*, 530 U.S. 363, 377-79 (2000) (preemption is appropriate even if the state and federal governments share a "common goal"); *Abdu-Brisson v. Delta Air Lines, Inc.*, 128 F.3d 77, 86 (D.C. Cir. 1997) (same where state and federal governments share common interests in the enforcement or interpretation of

federal law). *Cf. Verizon Commun., Inc. v. Law Offices of Cutis V. Trinko, LLP*, 124 S. Ct. 872, 881 (Jan. 13, 2004) (the existence of a federal regulatory scheme “designed to deter and remedy” an identified harm weighs heavily against inferring an overlapping judicial remedy).

The Government also appears to have overlooked what it told the Supreme Court in *Buckman* about the significance of a claim of fraud on a federal agency. In the Solicitor General’s *amicus* brief to the Court in *Buckman*, the Government stated that the “obligation to provide accurate information to a federal regulatory agency” implicates an “overriding and longstanding federal interest.” *Buckman* DOJ Br. at 17-18. Presaging the ultimate ruling in *Buckman*, DOJ declared that the “field involving an individual’s obligations to the federal government, and more particularly an individual’s obligation to provide accurate information to a federal regulatory agency, is not one ‘which the States have traditionally occupied.’” *Id.* at 18. If “federal regulatory agencies are to perform the important functions assigned to them by Congress,” the Government stated, they must be able to decide, “free from the hindrances imposed by state law,” how to obtain the information they need and how to sanction those who fail to provide it. *Id.* Because the plaintiffs’ claims of fraud on a federal agency involved a “paramount federal interest,” the Government concluded that “the presumption against preemption disappears and the likelihood of a fatal conflict between state and federal law significantly increases.” *Id.* at 19. This is no less true in this case because the FDA regime in *Buckman* was different or because the States share an interest in or stand to benefit from accurate best price reporting. This case still involves a claim of fraud on a federal agency.

The presumption against preemption also does not apply because, as in *Buckman*, the federal government -- not the States -- has an extensive mechanism for interpreting the rebate statute and the HHS Agreement, auditing compliance with these obligations, establishing a

dispute resolution process, and taking enforcement action against violations. Contrary to the Government's general point about the States' "historical role" in Medicaid fraud (Govt. Br. at 12), the States play *none* of these roles with respect to the Medicaid rebate program. The Government does not dispute, for example, that HHS is empowered to impose monetary penalties "for failure to provide timely information on AMP [or] Best Price" at a rate of \$10,000 per day of delay; or that HHS can "survey" manufacturers to verify best prices; or "impose civil monetary penalties" up to "\$100,000 for each item" if a manufacturer "refuses a request for information" or "knowingly provides false information." *See* 42 U.S.C. § 1320(a)(7); 42 U.S.C. § 1396r-8(b)(3)(B); Rebate Agreement §§ III(b), IV(c) (Ex. 2). Indeed, as the Government recognizes (Govt. Br. at 6), CMS promulgated a proposed rule that expressly discussed the Secretary's authority to survey and audit manufacturer records. *See* 60 Fed. Reg. 48465 (Sept. 19, 1995). CMS also recently published a proposed final rule to establish a uniform time frame in which manufacturers were required to submit revised pricing data and retain relevant pricing record. *See* 68 Fed. Reg. 51912 (Aug. 29, 2003).

The Government downplays the significance of these audit powers, quibbling that the Medicaid rebate program "is not specifically designed for identifying fraud" and that no "systematic review" exists for reviewing best price calculations. Govt. Br. at 14. But the question is whether the federal government has constructed an extensive federal audit, investigative, and enforcement mechanism, not whether the federal enforcement scheme is the most extensive possible or whether the States could provide assistance in auditing compliance with the rebate program. *See Buckman*, 531 U.S. at 347 (state law claims preempted in view of extensive federal system). In any event, the Government improperly downplays the role of the HHS Office of Inspector General in the Medicaid drug rebate program -- the OIG frequently

performs audits of manufacturers under the program. *See, e.g.,* HHS OIG, *Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs* at 4 (May 8, 1998) (discussing multiple audits of manufacturer best price and AMP calculations) (Ex. 3).³

The Government also downplays the dispute resolution process under the Medicaid rebate program by referring to it only in a footnote (Govt. Br. at 4 n.4). But this process is significant for preemption purposes because, under the Rebate Agreement, a State has a role in rebate disputes only if a manufacturer disputes the utilization information provided by a State. *See* Ex. 2 at §§ V(c), (f). Indeed, the *Best Practices Guide for Dispute Resolution* published by CMS describes the Medicaid rebate enforcement options available to HHS, but does not recite *any* enforcement role for States beyond “dispute resolution.” *See* CMS, *Best Practices Guide for Dispute Resolution* at 5 (1999) (Ex. 4) (excerpt). And CMS has even dictated the kinds of disputes that manufacturers and States can resolve. *HCFA/CMS Medicaid Drug Rebate Program Release No. 19* at 1 (Oct. 5, 1995) (Ex. 5), (limiting disputes to “utilization data and not [] unit rebate amounts or Medicaid reimbursement.”). In this *Program Release*, CMS admonished States and manufacturers that they “assume the risks of audits and potential Federal recoupment actions by settling disputes on any basis other than units”; and CMS told the States that they “do[] not have the authority to terminate a labeler.” *Id.* States

³ The Government’s assertion that the rebate statute contemplates state law enforcement actions because it refers to “other penalties as may be prescribed by law” (Govt. Br. at 5, quoting 42 U.S.C. § 1396r-8(b)(3)(c)(ii)), overlooks the fact that the next sentence of the statute cites only a federal remedy, 42 U.S.C. § 1320a-7a. This section certainly does not support an inference that Congress intended to establish a right of action for States.

instead should advise CMS if a labeler does not pay rebates, because *only* “the Secretary of DHHS retains the authority . . . to determine when termination action is necessary.” *Id.*⁴

The Government also never explains how the States could have a “traditional” role in enforcement of the rebate statute if they do not even receive the best price data from CMS. The Government concedes that only CMS receives best price data from manufacturers (Govt. Br. at 15), and that CMS does not disclose it to the States. It is presumably for this reason that Montana and Nevada never allege the best prices reported by any particular company -- they cannot do so because they do not know what prices actually were reported to CMS. *See* Mont. 2d Am. Cplt. ¶ 612; Nev. Am. Cplt. ¶ 392. CMS may have promulgated its confidentiality policy for the “efficient administration of the program,” as the Government suggests (Govt. Br. at 14), but the Government never explains how Congress could have intended to foster state enforcement of the Medicaid rebate program when the States do not even know what the reported best prices are.⁵

Finally, the “presumption against preemption” is even less appropriate here than in *Buckman* because the best price obligations flow from a federal contract. Obligations “to the United States under its contracts” are one of the “few areas” involving such “uniquely federal

⁴ Further, in *Program Release 71*, CMS stated that it is responsible for addressing a manufacturer’s failure to fulfill its obligations under the Rebate Agreement. There, CMS stated that “we are aware of a few manufacturers that unreasonably and routinely withhold rebate payments or fail to pay interest. We will continue our efforts to address these isolated problems.” *HCFA/CMS Medicaid Drug Rebate Program Release No. 71* at 4 (Nov. 20, 1997) (Ex. 6). *See also HCFA/CMS Medicaid Drug Rebate Program Release No. 86* at 2 (Dec. 11, 1998) (Ex. 7) (instructing States encountering “any obstacles to resolving disputes” to “contact the appropriate regional office drug rebate coordinator” for the intervention of CMS).

⁵ Massachusetts misleadingly suggests that States receive best price data from drug manufacturers (Mass. Br. at 6), but as the United States acknowledges (Govt. Br. at 14), CMS has determined that “the pricing data CMS receives is held in the strictest confidence,” and “actual pricing data goes no farther than CMS.” CMS, *Medicaid Drug Rebate Operational Training Guide* at D2 (Sept. 2001) (Ex. 8) (excerpts).

interests” that “are so committed by the Constitution and laws of the United States to federal control that state law is preempted and replaced, where necessary, by federal law.” *Boyle v. United Technologies Corp.*, 487 U.S. 500, 504 (1988). Indeed, in its *Buckman* amicus brief, the Government agreed that “the obligations and rights of the United States under its contracts” are governed “exclusively by federal law” and “involve uniquely federal interests.” *Buckman* DOJ Br. at 19-20.⁶

II. STATE LAW BEST PRICE CLAIMS ARE PREEMPTED BECAUSE AN EXTENSIVE MECHANISM FOR FEDERAL ENFORCEMENT EXISTS AND PERMITTING THE CLAIMS WOULD UPSET THE DELICATE BALANCE OF FEDERAL STATUTORY OBJECTIVES.

Citing two cases decided more than forty years ago, the Government first seeks to apply the wrong test for implied field preemption, the “physical impossibility” test. *See* Govt. Br. at 6. Instead, as the Supreme Court and the First Circuit have made clear far more recently, state law is impliedly preempted when it “interposes an obstacle to the achievement of Congress’s discernible objectives,” *Grant’s Dairy Maine LLC v. Commissioner of Maine Dep’t of Agriculture, Food & Rural Resources*, 232 F.3d 8, 15 (1st Cir. 2000), or “interferes with or is

⁶ The Court need not address Massachusetts’ assertion that because the Rebate Agreement indirectly benefits States, the States are entitled to enforce its terms under federal law as “third-party beneficiaries.” *See* State Br. at 5-7. This theory of relief was not advanced by Montana or Nevada. In any event, this argument is incorrect as a matter of law. The mere fact that a contract confers benefits on a third-party does not make it a “third-party beneficiary” for enforcement purposes. *See InterGen N.V. v. Grina*, 344 F.3d 134, 147 (1st Cir. 2003), citing *McCarty v. Azure*, 22 F.3d 351, 362 (1st Cir. 1994). Third-party beneficiary status requires -- at a minimum -- an explicit understanding between the parties that the contract is being entered into for the specific purpose of benefiting a third party. *McCarty*, 22 F.3d at 362. Here, although States receive a benefit through the rebate program, these payments have no bearing on why manufacturers sign the Agreement, and HHS signs it to preserve uniformity regarding the terms of the Medicaid drug rebate program. The benefits accruing to the States are ancillary to the parties’ purposes, and do not support third-party beneficiary status. *Id.* Because it is not a State, Suffolk County’s claim that it is a third-party beneficiary of the Rebate Agreement has even less force than Massachusetts’s does. *County of Suffolk v. Abbott Laboratories, Inc., et al.*, 01-CV-12257-PBS.

contrary to federal law.” *Gade v. National Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 89 (1992) (citation omitted). The Government also overlooks the *Buckman* preemption test that applies when state law claims allege fraud on a federal agency -- the claims are preempted when (1) an “extensive mechanism” for federal enforcement exists, and (2) permitting the state law claims would “upset the delicate balance” of federal statutory objectives. 531 U.S. 341, 347-53.

Likewise, the Government incorrectly asserts that preemption is appropriate only if an actual conflict is apparent on the face of the plaintiff’s allegations. In *Buckman*, the Supreme Court did not require any **actual** conflict for preemption to occur -- the conflict “stem[med] from the fact that the federal government had the authority to ‘punish and deter fraud,’” and “state-law fraud-on-the-FDA claims **inevitably** conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.” *Id.* at 350. In this case, the fraud-on-CMS claims “inevitably conflict” with the federal government’s ability to determine if it has been defrauded and injured.

In any event, even if an actual direct conflict was required (which it is not), there already is a conflict in the States’ best price claims. For example, Massachusetts claims in its consolidated lawsuit that one defendant, Warrick Pharmaceuticals Corporation, “materially understated” its AMP reports to CMS for the drug Albuterol in a 90 mcg dosage. *See Complaint of the Commonwealth of Massachusetts* ¶ 79 & Ex. D (Sept. 25, 2003). In contrast, Montana and Nevada allege that, for the same drug and dosage, Warrick “did not report the actual . . . ‘average manufacturer’s price’ [to CMS], but instead . . . reported higher prices and . . . excluded discounts.” *Mont. 2d Am. Cplt.* ¶ 674 & Ex. A; *Nev. Am. Cplt.* ¶ 473 & Ex. A. These claims cannot both succeed under any uniform definition of “AMP,” and it is impossible for Warrick (or any manufacturer) to satisfy simultaneously the objections raised by these States. Likewise,

Montana and Nevada assert that the value of unidentified “educational grants” should have been included in the best price calculation (Mont. 2d Am. Cplt. ¶ 612; Nev. Am. Cplt. ¶ 392), but the rebate statute imposes no such broad obligation. If the state law best price claims are not preempted, conflicts like this will only proliferate. This is why the *Buckman* court recognized that if States are permitted to determine whether submissions to a federal agency violate state statutes, based on state-specific definitions of falsity and deception, then inevitably different courts will reach different conclusions, and, “as a practical matter, complying with [HHS’] detailed regulatory regime in the shadow of 50 States’ [laws]” will be impossible. 531 U.S. at 348, 350.

Remarkably, the Government concedes that state law best price claims likely will result in different States reaching different conclusions about what constitutes a “best price,” but suggests that this is not significant. *See* Govt. Br. at 16-17. Even though the Government admits that manufacturers may be required to report “state-specific best prices to CMS” (*id.*), the Government asserts that this would be inconsequential because CMS can handle the recalculations and manufacturers already “contend with some state rebate variation with regard to prior authorization programs, formularies, or supplemental rebate agreements.” *Id.* But prior authorizations, formularies, and supplemental rebates are requirements imposed by States entirely outside of the Medicaid rebate program -- they have nothing to do with manufacturer best price calculations to CMS. More importantly, the Government disregards the key underpinning of the rebate program, which is the calculation of a uniform, nationwide rebate amount for each covered drug and dosage. The rebate statute requires manufacturers to report a single, nationwide best price for each covered drug and dosage to CMS (42 U.S.C. § 1396r-8(b)(3)(A)). This best price, in turn, is used to determine the single, nationwide Unit Rebate

Amount (“URA”) that forms the basis for the rebates. To instead require “state-specific” best price reports would result in state-specific URAs and, thus, state-specific rebate amounts. This outcome would undermine the Medicaid rebate program’s bedrock requirement that rebates for each drug and dosage are to be based on the same formula *nationwide*. Moreover, the Government’s proposal would also increase the number of manufacturer best price reports significantly. Although the Government dismisses the burden this would create (Govt. Br. at 16-17), such a proliferation of reports will overtax the resources of the manufacturers forced to produce them and the agency forced to analyze them.⁷

Next, the Government asserts that we “overstate” the likelihood of a “patchwork of liability” because “guidance” from CMS “will naturally limit the amount of state, or federal, court variation” in deciding best price claims. *Id.* at 17-18. In other words, the Government purports to assure the Court that preemption is unnecessary because the States and state court judges will “naturally” and uniformly recognize and defer to “guidance” from CMS on best price issues, thus ensuring that myriad state court decisions will coalesce into some uniform body of law. *Id.* Not only is this obviously unrealistic, but it contradicts the Government’s own position in *Buckman*, where it argued successfully in favor of preemption precisely because “fraud-on-the-FDA claims would permit juries in different States to reach different judgments that differ from FDA’s concerning whether an entity has actually committed fraud on the FDA.” *Buckman* DOJ Br. at 23. As the Government further recognized, “[a] multiplicity of tribunals and a

⁷ Requiring state-specific best prices would also interfere with Section 340B of the Public Health Service Act, which entitles certain public health entities to drug pricing that is based on the Medicaid drug rebate amount and is calculated using manufacturers’ single, nationwide best prices AMPs. 42 U.S.C. §§ 256b(a)(1)-(2). Like the Medicaid rebate program, the administration of this public health program would also be hopelessly disrupted by the advent of state-specific best prices.

diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law.” *Id.* (quoting *Garner v. Teamsters*, 346 U.S. 485, 490-491 (1953)). DOJ was correct in *Buckman*, as the notion that the States and state courts will enforce the rebate statute consistently according to CMS guidance cannot be taken seriously. Moreover, if the mere availability of “guidance” from a federal agency were sufficient to ensure uniformity in the interpretation of federal law, then “conflict” preemption would never be justified.

The Government then asserts that even if States or state courts reach inconsistent results, the CMS interpretation “would be dispositive and preclude state court action to the contrary.” Govt. Br. at 18 n.10. But the Government never explains how CMS could “preclude” state court action or make its views “dispositive” in this situation. And if CMS’ views of the rebate statute are “dispositive” and preclusive of state court action, then the States’ claims should be preempted. *See, e.g., Buckman*, 531 U.S. at 347.

The Government also ignores its own argument in *Buckman* that claims of fraud on a federal agency “conflict with the important federal interest in permitting [the agency] to decide for itself whether it has been defrauded, and, if so, what remedy to seek.” *Buckman* DOJ Br. at 21. The Government asserts that the Montana and Nevada state actions may not “yet second-guess[] any agency determination” (Govt. Br. at 16), but the conflict is apparent from the fact that the States are seeking to remove HHS as the arbiter of what is an appropriate best price submission. In *Buckman*, DOJ told the Supreme Court that if a State attempted to “monitor fraud on the FDA” and “devised its own set of sanctions for punishing such fraud,” the conflict between that system and the federal interest in uniform enforcement “would be apparent.” *Buckman* DOJ Br. at 24. This “sharp conflict,” the Government concluded, would not be

“lessened simply because the state scheme for regulating fraud on the FDA takes the form of a common law cause of action.” *Id.* This is no less true here.

The Government further ignores the fact that state law best price claims distort the penalty scheme established by the rebate statute. In its *Buckman* brief, the Government warned that “‘since remedies form an ingredient of any integrated scheme of regulation, to allow the State to grant a remedy . . . which has been withheld from [HHS] . . . accentuates the danger of conflict.’” *Id.* at 23 (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)). Here, although the rebate statute contains a range of possible remedies against manufacturers for the submission of fraudulent best price data, these remedies do *not* include the unrestricted punitive damages sought by Montana (2d Am. Cplt. Count V, ¶¶ 692-93) and Nevada (Am. Cplt. Count VI, ¶¶ 478-79). Relatedly, state law best price claims also interfere with HHS’ discretion to decide which of its statutorily prescribed remedies to pursue for fraud, if any. *See Buckman* DOJ Br. at 24. Because best price violations amount to fraud on HHS, it is “vital” that enforcement “should be exclusively within the control of the Federal Government.” *Id.* (quoting *Pennsylvania v. Nelson*, 350 U.S. 497, 505 (1956)).

Finally, the Government warned in *Buckman* that permitting state law claims for fraud on the FDA would impose undesirable practical consequences on the agency and regulated manufacturers, all of which apply equally here. *See Buckman* DOJ Br. at 28-29. The Government now ignores these consequences, but as was true in *Buckman*, state law best price claims would invite “highly intrusive inquires” into HHS’ internal deliberations. *Id.* at 28. For example, Montana and Nevada assert that the manufacturers concealed their allegedly fraudulent best price submissions. *See* Mont. 2d Am. Cplt. ¶¶ 635-43; Nev. Am. Cplt. ¶¶ 404-12. In litigating this issue, the parties presumably will seek discovery from HHS about agency officials’

knowledge and the courses of action they might have taken under various scenarios. As the Government acknowledged in *Buckman*, “widespread litigation could be expected” on whether testimony and other evidence could be obtained from HHS, and such litigation would divert HHS’ resources and distort its decision-making processes. *See Buckman* DOJ Br. at 29.

CONCLUSION

For the foregoing reasons, and for the reasons set forth in the opening and reply briefs on the motions to dismiss the Montana and Nevada Complaints, the state law best price claims should be dismissed as preempted by the Medicaid rebate statute.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 9, 2004, I caused a true and correct copy of this Defendants' Brief in Response to the Amicus Briefs of the United States and the Commonwealth of Massachusetts to be served on all counsel by Verilaw electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL No. 1456.

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